NOVARTIS

Technical Steward

Job ID
REQ-10087620

九月 13, 2026

China

摘要

Provide specialist knowledge and expertise regarding aseptic manufacturing technology and validation requirements.
Works as aseptic manufacturing technology SME in major aseptic product technical transfer projects.
Oversee processes and standards to maintain and improve existing and to implement new innovative manufacturing technologies.

About the Role

Major accountabilities:

Technical Transfer Lead

- Design Phase. Actively participate facility and equipment design and selection. Review the URS, design concepts, layouts and technical specifications for facility, equipment and utilities

from GMP and aseptic technology perspective. Contribute to contamination control strategy (CCS) development for the new sterile facility.
- Construction and Commissioning. Provide aseptic processing inputs during construction, installation and commissioning activities to ensure alignment with approved design and GMP requirements. Participate in or review FAT/SAT activities for critical equipment and systems.
- Qualification and validation. Work with site validation lead and other SMEs on qualification/validation activities regarding sterile product LCM projects in aspects of facility, HVAC, utilities, equipment, cleaning, sterilization, aseptic manufacturing processes.

Product Steward

- Act as the SPOC for the interface with global MS&T network and with technical development organization, for the corresponding global activities, to define and implement new technical standards for existing and new technologies and equipment.
- Owns the knowledge of specific pharmaceutical manufacturing process technologies, locally, including any pilot scale, scale up or down, and Design of Experiments (DoE).
- Participate in the definition and selection of pharmaceutical equipment, through providing input to User Requirements.
- Collaborate with technical development, other sites and global MS&T network to facilitate transfer of technical knowledge.
- Assure that the necessary benchmark is done internally in Novartis, and externally in the scientific and academic environment, in order to stimulate and to extend the knowledge, increasing the know-how of the associates and expanding it to the rest of the organization.
- Be a recognized scientific expert internally and externally by reporting and presenting scientific/technical work at internal/external meetings/conferences and publish in peer reviewed international scientific journals including patents.
- Maintain their work in inspection readiness level.
- Support Product Stewards in creation of Quality Risk Assessments.
- Support creation of SOPs for Process Unit.
- Provide technical expertise to Engineering for design activities in Capex projects around technologies within area of responsibility.

- Provide technical expertise for equipment qualification around technologies within area of responsibility.

Validation

- Approve validation reports under their area of responsibility (as needed) e.g. packaging validation.
- Provide technical expertise for validation activities around technologies within area of responsibility.

Manufacturing Excellence- for the technology(ies) assigned

- Harmonize and optimize technical processes across the site.
- Benchmark new technologies and equipment relevant for site.
- Designs and controls optimization projects.
- Provide SME expertise to perform process characterization of the related pharmaceutical processes to increase robustness and sustainability.
- Support Product Stewards / Process Experts in trouble shooting / root cause investigation by

providing second level of specialist expertise as SME and by harmonising and optimising related technical processes across the units.
- Perform technical feasibility trials related to process improvement and implementation of new manufacturing technologies.

Training

- Own the Training Curriculum for own Job Profile and direct reports.
- Provide technical trainings and education programs for Process Experts and Production Operators.

Novartis Manufacturing Manual

- Support implementation of Novartis Manufacturing Manual principle 3.
- Provide SME input to Novartis Manufacturing Manual principle 4.
- Represent site in technical stewardship network.

Key performance indicators:

- Success rate of qualifications and validations for aseptic product technical transfers.
- Success rate of aseptic product transfer projects.
- Batch release on time/in quality.- aseptic product related.
- Line throughput time. - aseptic product related.
- Deviations - aseptic product related.
- Effective CAPAs-aseptic product related.
- Ppk/CpK - aseptic process capability.
- OoS, OoE - Out of Specification, Out of Expectation -aseptic process related.
- Yield.-aseptic product related.
- Customer Complaints - aseptic process related.
- Recalls - aseptic process related.
- Success rate of internal audits and Health Authorities' inspections.- aseptic product related.

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients ' lives. Ready to create a brighter future together? https://www.novartis.com/about/strategy/people-and-culture

Benefits and Rewards: Learn about all the ways we ' ll help you thrive personally and professionally. Read our handbook (PDF 30 MB)

部门
Operations

Business Unit
Production / Manufacturing

地点
China

站点
Changping County (Beijing)

Company / Legal Entity
CN06 (FCRS = CN006) Beijing Novartis Pharma Co., Ltd

Functional Area
Technical Operations

Job Type
Full time

Employment Type
Regular

Shift Work
No

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alongside;('alongside', 'hidden', 'over') expandOnFirstPlay: false, showTime: true, downloadDisabled: false, printDisabled: false, disable: true }; } if (kPlayer.plugins["preventSeek"]) { config.plugins.preventSeek = { preventSeekForward: false, preventSeek: false }; } config.plugins.floating = { disable: true }; if (kPlayer.plugins["navigation"]) { config.plugins.navigation = { position: "right", expandMode: "over", expandOnFirstPlay: false, visible: false }; } if (kPlayer.plugins["hotspots"]) { config.plugins['playkit-js-hotspots'] = { disable: true }; } if (kPlayer.plugins["moderation"]) { config.plugins['playkit-js-moderation'] = { disable: true }; } if (kPlayer.plugins["info"]) { config.plugins['playkit-js-info'] = { disable: true }; } if (kPlayer.plugins["share"]) { config.plugins.share = { disable: true }; } config.ui.uiComponents = []; if (kPlayer.plugins["googleAnalytics"]) { config.plugins.googleTagManager = {}; config.plugins.googleTagManager.customEventsTracking = {}; config.plugins.googleTagManager.containerId = 'GTM-57RJQ5'; config.plugins.googleTagManager.customEventsTracking.custom = []; config.plugins.googleTagManager.customEventsTracking = { preset: { coreEvents: true, UIEvents: false, playlistEvents: false, castEvents: false } }; }

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